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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Fred ZACOUTO et al.

Group Art Unit: 3738

Appln. No. : 10/040,429

(Continuation of US application 09/200,855)

Examiner: B. Snow

Filed : January 9, 2002

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TC 3738 MAIL ROOM

For : SKELETAL IMPLANT

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to the duty of disclosure set forth in 37 CFR 1.56 and in accordance with the provisions of 37 CFR 1.97 and 1.98, Applicants hereby wish to bring to the Examiner's attention the following documents which were made of record in U.S. parent patent application 09/200,855, of which the instant application is a continuation, and which are cited for the Examiner's consideration.

(1) U.S. Patent No. 3,648,294 (SHARESTANI), issued on March 14, 1972, discloses an endoprosthesis having two parts connected to bone parts, with a cylinder and a piston operatively separated by a damping, namely shock absorbing device. There is no means, nor suggestion, to modify by control, the viscosity of the device, nor other parameter.

(2) U.S. Patent No. 4,206,517 (PAPPAS et al.), issued on June 10, 1980, discloses an endoprosthesis having two parts which make use of body fluid present in the prosthesis to provide hydraulic action for reducing the amount of shock loads. No control is possible.

(3) U.S. Patent No. 4,932,969 (FREY et al.), issued on June 12, 1990, discloses an intervertebral prosthesis formed of a compressible hollow body in which an incompressible fluid can be transferred from one edge to the other by compressive loadings to avoid tensile forces. This device is also completely passive. US '969 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(4) U.S. Patent No. 4,932,975 (MAIN et al.), issued on June 12, 1990, discloses a vertebral prosthesis whose two end parts are connected by means allowing limited resilient axial and torsional movements. US '975 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(5) European Patent No. 0 385 929 (JAQUET ORTHOPEDIE S.A.), published on September 5, 1990, and corresponding U.S. Patent No. 5,207,676 (CANADELL et al.), issued on May 4, 1993, disclose an external fixator for connecting two bone elements to authorize an axial movement between the two parts connected to the bone elements with elastic means for limiting the load on the bone elements during axial movements. The elastic means consists of a spring whose preloading can be adjusted by external adjustment means (screw), and axial displacement and axial limited reciprocation are secured by connecting the

fixator to an electric motor means. There is no teaching which could be useful for an endoprosthesis.

(6) U.S. Patent No. 5,002,576 (FUHRMANN et al.), issued on March 26, 1991, discloses an intervertebral disk endoprosthesis having a corrugated tube, or bellow, filled with a viscoelastic material, such as silicone. This device is totally passive. US '576 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(7) German Utility Model (Gebrauchsmuster) No. G 92 09 584.4 (DIDZUN et al.), published on January 7, 1993, is believed to be no more relevant than SHARESTANI, supra, but is cited for the Examiner's consideration.

(8) French Patent Publication No. 2 693 650 (SIMON), published on January 21, 1994, is believed to be no more relevant than SHARESTANI, supra, but is cited for the Examiner's consideration.

(9) U.S. Patent No. 5,375,823 (NAVAS), issued on December 27, 1994, discloses an intervertebral stabilization device using passive elastomeric damping cushions. US '823 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(10) International Patent Publication No. WO 94/06364 (DYNASTAB LIMITED PARTNERSHIP), published on March 31, 1994, discloses an external stabilizer which can be axially elongated by introducing an hydraulic liquid in a chamber. Passive damping is obtained by a partition in the chamber and by a pneumatic chamber separated from the liquid

chamber by a deformable membrane. The loads on the bone elements can be monitored by a pressure sensor in the chamber. A remotely controlled external manipulator can be connected to the stabilizer to allow to correct displacement of fractured bone fragments to which the stabilizer is connected. Passive damping is disclosed and no teaching is provided that could be useful for an endoprosthesis.

(11) U.S. Patent No. 5,376,138 (BOUCHARD et al.), issued on December 27, 1994, discloses a hydraulic device for correcting the gait of a femoral amputee, to form an external shock absorber. The shock absorber comprises a hydraulic cylinder and a piston, and valve means to block off a fluid communication upon undesirable movement of the wearer. Damping can be externally adjusted. This device is passive and provides no teaching which could be useful for an endoprosthesis. US '138 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(12) U.S. Patent No. 5,389,107 (NASSAR et al.), issued on February 14, 1995, discloses a shock absorbent prosthetic hip joint with a resilient device. US '107 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(13) U.S. Patent No. 5,423,816 (LIN), issued on June 13, 1995, discloses an intervertebral locking system which allows passive axial and torsional movement through a spiral elastic body. US '816 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(14) French Patent Publication No. 2 723 841 (GAUCHET et al.), published on March 1, 1996, discloses an intervertebral disc prosthesis having two end parts connected by a deformable resilient wall forming a chamber in which a slightly compressible fluid secures a damping effect. This device is completely passive.

(15) European Patent Publication No. 0 677 277 (MOREAU et al.), published on October 18, 1995, discloses a passive solid viscoelastic intervertebral prosthesis with a passive damping effect. There is no teaching of use for the invention.

(16) French Patent Publication No. 2 681 525 (DOMINIQUE), published on March 26, 1993, is cited as being pertinent for reasons cited by the Examiner in the parent application in the Office action of August 21, 1998.

(17) Reanimation and Artificial Organs, Scientific Journal of Medicine, Surgery, Cellular Biology and Related Physics, Vol. 11, No. 1, October 3, 1996, Paris, France, pages 1-15, includes information to which the inventors contributed. This document was published after the filing date of the two priority documents on which the instant application is based.

(18) "Des amortisseurs et une suspension pour des prothèses osseuses intelligentes", Dr. Mara NGUYEN, an article from a French language medical newspaper entitled Le Quotidien Du Médecin, No. 5931, October 17, 1996, describes an invention of one of the inventors, Dr. Zacouto, of the instant application.

(19) Reanimation and Artificial Organs, Scientific Journal of Medicine, Surgery,

Cellular Biology and Related Physics, Vol. 12, No. 1, December 1997, Paris, France, pages 1-12, includes an editorial by Dr. Zacouto and two articles by inventors of the instant application. This issue was published after the priority date of the parent application, but less than twelve months before the instant continuation-in-part application.

(20) "An Active Orthopaedic Implant with Variable Visco-Elastic Behavin and Adjustable Alignment," Zeller, Zacouto, Canal, and Viguier, 51st International Meeting on Advanced Spine Techniques, IMAST May 1-3, 1998.

(21) U.S. Patent No. 5,720,746 (SOUBEIRAN), issued on February 28, 1998, was cited by the Examiner in the parent application in the Office action of August 21, 1998. Disclosed therein is an implantable prosthesis having two end parts to be secured to bone elements and which are axially movable. A means, such as a spring, applies a constant force to move one part in a given axial direction. One part has a projecting portion which protrudes into a material contained in the other part, which material is suitable for passing from an undeformable hard state, where the projecting portion, and hence, the first part, is blocked, to a soft deformable hard state where the first part may move under the action of the spring, while the material creeps around the projecting portion. Softening is achieved by heating means such which are controlled by a magnetic external fluid. The device has several drawbacks. Movement is only axial and is not reversible, which would make it unsuitable for arthrosis purposes. Higher energy transfer is needed to soften the material.

Allowing the material to cool to return to the first hard state needs time and, thus, does not allow substantial control of the displacement between a first and a second position. Duration of the force action cannot be substantially controlled. No damping effect is obtained. Local increase in temperature of a substantial mass in an implanted device is undesirable. This document gives no useful teaching for the invention as claimed. US '746 was cited by the Examiner in the parent application in the Office action of August 21, 1998.

(22) US patent 5,626,579; Muschler et al.

(23) US patent 5,720,746; Soubeiran

(24) US patent 5,071,435; Fuchs et al.

(25) US patent 5,360,016; Kovacevic

(26) US patent 5,466,261; Richelsoph and

(27) US patent 4,921,499. Hoffman et al.

Copies of the above-listed documents (1)-(27) are not enclosed herein since these documents were made of record in the parent application and copies were provided therein. However, a completed copy of the PTO-1449 Form listing documents (1)-(27) is being provided. If the Examiner has any difficulty in obtaining copies of any of the references cited, Applicants will be happy to provide copies of those documents. Accordingly, the Examiner is requested to consider these documents and to indicate such consideration by returning a signed and initialed copy of the PTO-1449 form with the first official

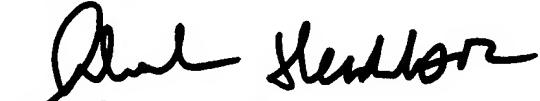
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communication.

Applicants note that this Information Disclosure Statement is being filed before the mailing date of a first office action on the merits. Accordingly, consideration of the enclosed document is required under 37 C.F.R. 1.97(b)(3).

Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,
Fred ZACOUTO et al.


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April 9, 2002
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